

**REMARKS**

Allowable Subject Matter

Claims 28 has been objected to as being dependent upon a rejected base claim but otherwise indicated as allowable. Applicant reserves the right to rewrite the claim to include all of the limitations of the rejected base claim and any intervening claims in the event those claims are not allowed.

Claim Rejections

Claims 1-27 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable in view of the cited art. Specifically, claims 1-9, 11, and 16-18 (Office Action ¶¶ 4-8) and claims 19-21 and 23-27 (Office Action ¶¶ 15-20) have been rejected over Anne (US 2002/0160439 A1) in view of Paul ("Effects of Oxidizing Adulterants. . . ." JAT, Vol. 26, October 2002)(hereinafter "primary combination"). Claim 10 has been rejected in view of this primary combination in further view of Kightlinger (US 4,558,100)(Office Action ¶¶ 9-10); claims 12-15 rejected in view of the primary combination in further view of Banerjee ("Urinary Hydrogen Peroxide . . . ")(Office Action ¶¶ 11-14); and claim 22 also rejected in view of the primary combination in further view of Banerjee (Office Action ¶¶ 21-22). Applicant respectfully traverses.

In order to make out a prima facie case of obviousness, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1970). The mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggest the desirability of the combination. *In re Mills*, 16 USPQ.2d 1430 (Fed. Cir. 1990). Further, a prior art reference must be considered in its entirety, i.e, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Assoc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983).

The Supreme Court recent confirmed the obviousness inquiry. In the *KSR* case, the Supreme Court reiterated that the framework for applying the statutory language of 35 U.S.C. 103 was set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966):

the scope and content of the prior art are to be determined; differences between the prior art and the claims in issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the subject matter sought to be patented.

*KSR Int'l v. Teleflex Inc.* (U.S. 2007). Although the Supreme Court held that the Teaching, Suggestion, Motivation (TSM) test is not the flexible test required by *Graham*, the Court noted that rejections based on obviousness grounds cannot be sustained by mere conclusory statements.

The Supreme Court stated that a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way that the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what is already known. By asserting that a claimed combination is obvious to try, there should be demonstrated both (1) a design need or market pressure to solve a problem and (2) a finite number of identified, predictable solutions.

In the present application, the prior art relied upon in the Office Action does not suggest the combination as applied to the claims. In fact, it teaches away from the present invention. Specifically, Anne's procedure (US 2002/0160439 A1) was based on direct interaction between a limited number of oxidants and a few select chromogenic compounds. However, as pointed out in Applicant's specification at paragraph [0032] and in a subsequent publication of the present inventor Paul (J. Anal. Toxicol. 28: 599-608, 2004)("JAT-2004"), several oxidizing agents (periodate, persulfate, hydrogen peroxide, Oxone<sup>®</sup>, organic peroxides) either do not react or react poorly with the chromogenic compounds mentioned in Anne. More importantly, Anne does not mention the use of ferrous ion as an intermediate. In essence, the primary combination of prior art would result in a chemical mechanism completely contrary to Anne's direct interaction method of measurement.

The importance of the intermediate cannot be understated. The mechanism of the chemical reaction of the present invention is very different from that of Anne. As stated in the MPEP, if a proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP § 2143.01 (*citing In re Ratti*, 270 F.2d 810 (CCPA 1959)). Accordingly, since Anne operates via a different chemical pathway and teaches away from the primary combination, there is no *prima facie* case of obviousness.

In addition, the present inventor has shown that ferrous ion actually interferes with Anne's procedure when benzidines are used as chromogens (see JAT-2004). If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01 (*citing In re Gordon*, 732 F.2d 800 (Fed. Cir. 1984)). Thus, again, the primary combination would not be pursued by one of ordinary skill in the art and therefore there is no *prima facie* case of obviousness.

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Appl. No.: 10/827,282

**PATENT**

In view of the fact that the primary combination of Anne (US 2002/0160439 A1) in view of Paul ("Effects of Oxidizing Adulterants. . . ." JAT, Vol. 26, October 2002) has been shown to have been contrary to the teachings of the art, Applicant submits that the independent claims are patentable over this combination. Further, Applicant submits that none of the other references overcome the deficiencies in the combination as applied to the independent claims. Moreover, if an independent claim is non-obvious under 35 U.S.C. 103, then any claim depending therefrom is non-obvious. *In re Fine*, 5 USPQ.2d. 1596 (Fed. Cir. 1988). In view of the foregoing, Applicant respectfully submits that reconsideration and withdrawal of the outstanding rejections of claims 1-27 is proper and such action is respectfully requested.

Finally, Applicant wishes to note for the record that the Paul reference has an effective date of October 2002 and the present application claims priority back to US Provisional Application No. 60/479,187 filed on June 18, 2003. Accordingly, the effective filing date of the present application is less than one year after the publication date of the Paul reference, thereby affording Applicant the ability to present a properly filed Declaration Under 37 C.F.R. § 1.131 if applicable.

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**CONCLUSION**

In view of the above Remarks, Applicant respectfully submits that the present application is in condition for allowance and early notification of the same is earnestly requested. Should the Examiner have and questions of comments or otherwise deem that prosecution of the present application may be advanced, the Examiner is invited to contact Applicant's representative at the number below.

Respectfully submitted,  
CAHN & SAMUELS, L.L.P.

By:           /William E. Bradley/            
William E. Bradley, Esq.  
Reg. No. 42,355  
CAHN & SAMUELS, LLP  
1100 17<sup>th</sup> Street N.W.  
Suite 401  
Washington, DC 20036-4650  
Telephone No.: 202-331-8777  
Facsimile No.: 202-331-3838

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